

APR 27 2001

LSI SOLUTIONS  
Special 510(k) Premarket Notification  
LSI SOLUTIONS Flexible Suture Placement Device and Accessories Product

K011016  
Page 1 of 3

**J. 510(k) Summary of Safety and Effectiveness**

**Submitted By:** LSI SOLUTIONS

**Device Description:** The LSI SOLUTIONS Flexible Suture Placement Device and Accessories Product is a sterile, disposable, flexible device, which can be used in, but is not limited to, endoscopic procedures. This device has a flexible shaft and includes an optional vacuum accessory and Accessory Conduit.

**Trade Name:** LSI SOLUTIONS Flexible Suture Placement Device and Accessories Product

**Common/Usual Name:** Needle Guide

**Classification Name/Code:** Manual Surgical Instrument for General Surgery/  
GCJ

**Classification:** FDA has classified similar devices as Class II as per 21 CFR § 876.1500. This device falls within the purview of the General and Plastic Surgery Panel.

**Establishment Registration Number:** 1320468

**Sterility:** Validated EO cycle in accordance with AAMI Standard 11135 using an SAL of  $10^{-6}$  and EN 550.

**Performance Standards:** No performance standards applicable to the LSI SOLUTIONS Flexible Suture Placement Device and Accessories Product have been established by the Food and Drug Administration.

**Intended Use:** Used for approximation of soft tissue.

**Cleared Device:** The cleared device is the LSI Suture Placement device and accessories (K981531) which is manufactured by LSI SOLUTIONS.

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**LSI SOLUTIONS Flexible Suture Placement Device and Accessories Product**

**J. 510(k) Summary of Safety and Effectiveness (continued)**

**Substantial Equivalence:**

The LSI SOLUTIONS Flexible Suture Placement Device and Accessories Product is substantially equivalent to the referenced cleared LSI Suture Placement device and accessories in that it is identical with respect to technological characteristics and intended use.

<b>Characteristic</b>	<b>Cleared: LSI Suture Placement device and accessories (K981531)</b>	<b>Modified: LSI SOLUTIONS Flexible Suture Placement Device and Accessories Product [Subject of Special 510(k)]</b>
<b>Intended Use</b>	Approximation of soft tissue	Approximation of soft tissue
<b>Function</b>	The LSI Suture Placement device and accessories deliver suture materials to the site of application.	The LSI SOLUTIONS Flexible Suture Placement Device and Accessories Product delivers suture materials to the site of application.
<b>Materials</b>	The LSI Suture Placement device and accessories use biocompatible materials.	The LSI SOLUTIONS Flexible Suture Placement Device and Accessories Product uses biocompatible materials.
<b>Packaging</b>	The LSI Suture Placement device and accessories are disposable devices that are packaged in a thermoformed blister with a Tyvek <sup>®</sup> cover and in Tyvek <sup>®</sup> and Mylar <sup>®</sup> pouches.	The LSI SOLUTIONS Flexible Suture Placement Device and Accessories Product are disposable devices that are packaged in Tyvek <sup>®</sup> and Mylar <sup>®</sup> pouches.
<b>Sterility</b>	Sterile, Disposable	Sterile, Disposable

**Biocompatibility:**

Reasonable assurance of biocompatibility for the patient contacting and potential patient contacting materials has been established through an extensive history of use in similar medical devices and biocompatibility test results.

**J. 510(k) Summary of Safety and Effectiveness (continued)**

**Design Control/Risk Analysis/Design Verification:**

Design control, risk analysis and design verification activities for the subject of this Special 510(k) have been conducted in accordance with all applicable internal LSI SOLUTIONS procedures. The design control process employed is inclusive of the elements stipulated by 21 CFR § 820.30. The risk analysis performed identified the risks relative to the performance requirements, as specified by LSI SOLUTIONS internal procedure for risk analysis. The possible risk, risk code, probability of occurrence, severity (risk factor), comments, mitigation employed, the potential to detect (mitigation factor), mitigation effectiveness and LSI SOLUTIONS recommended actions, as appropriate, are also documented. During Design Verification, visual, dimensional and functional testing to ensure the performance and design integrity of this product was conducted. All results obtained during LSI SOLUTIONS Design Verification meet predetermined acceptance criteria for this product.



APR 27 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Christine E. Ehmann  
Regulatory Affairs Manager  
LSI Solutions  
2144 Brighton-Henrietta Town Line Road  
Rochester, New York 14623

Re: K011016

Trade/Device Name: LSI Solutions Flexible Suture Placement Device  
and Accessories Product

Regulation Number: 876.1500

Regulatory Class: II

Product Code: GCJ

Dated: March 9, 2001

Received: April 4, 2001

Dear Ms. Ehmann:

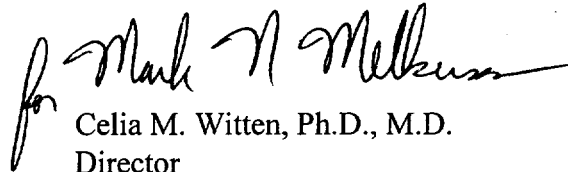
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark N. Melkerson", is written over the typed name of the signatory.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**LSI SOLUTIONS**  
**Special 510(k) Premarket Notification**  
**LSI SOLUTIONS Flexible Suture Placement Device and Accessories Product**

**K. Indications for Use**

510(k) Number (if known): K011016

Device Name:


LSI SOLUTIONS Flexible Suture Placement Device and Accessories Product

Indications for Use:

The LSI SOLUTIONS Flexible Suture Placement Device and Accessories product is used for the approximation of soft tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

510(k) Number K011016 ~~Over~~-The-Counter Use \_\_\_\_\_